



**EXHIBIT A TO SUBPOENA FOR PRODUCTION  
OF DOCUMENTS TO GALBRAITH LABORATORIES, INC.**

**DEFINITIONS**

1. For purposes of this subpoena and the Requests contained herein, the following terms shall have the following meanings:

a. "GALBRAITH," "You," or "Your" refers to GALBRAITH LABORATORIES, INC., and any of its predecessors in interest, successors in interest, parent-companies, subsidiaries, divisions, subdivisions, affiliates, officers, directors, employees, representatives, independent contractors, consultants, or agents, whether present or former, including attorneys and accountants.

b. "Ethicon, Inc." refers to Ethicon, Inc., and any of its predecessors in interest, successors in interest, parent companies, subsidiaries, divisions, subdivisions, affiliates, officers, directors, employees, representatives, independent contractors, consultants, or agents, whether present or former, including attorneys and accountants.

c. "Communication" means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise).

d. "Concerning" means relating to, referring to, describing, evidencing, embodying, or constituting.

e. "Document" is defined to be synonymous in meaning and equal in scope to the usage of this term in Federal Rule of Civil Procedure 34(a), including, without limitation, electronic data or computerized data compilations including all information that serves to identify, locate, or link such material, such as file inventories, file folders, indices, and Metadata. This term also refers, without limitation, to the original and all copies, prior drafts and

translations, written, printed, typed, photostatic, photographed, recorded, or otherwise reproduced communications, data compilations, or representations of every kind, whether comprised of letters, words, numbers, pictures, sounds, or symbols, whether prepared by manual, mechanical, electronic, magnetic, photographic, or other means, as well as audio, video or other recordings of communications, oral statements, conversations, or events. Furthermore, this term includes, but is not limited to, any and all of the following: correspondence, notes, minutes, records, messages, memoranda, telephone memoranda, diaries, contracts, agreements, invoices, orders, acknowledgements, receipts, bills, statements, appraisals, reports, forecasts, compilations, schedules, studies, summaries, analyses, pamphlets, brochures, advertisements, news articles, tables, tabulations, financial statements, working papers, tallies, maps, drawings, diagrams, pictures, film, microfilm, microfiche, computer-stored or computer-readable data, computer programs, computer printouts, telegrams, telexes, facsimiles, tapes, transcripts, recordings, and all other sources or formats from which data, information, or communications can be obtained. A draft or non-Identical Copy is a separate document within the meaning of this term.

f. "Electronic data" or "data" means the original (or identical duplicate when the original is not available), and any non-Identical Copies of writings and data compilations in any form, and of every kind and description, including electronically stored information or "ESI", whether inscribed by mechanical, facsimile, electronic, magnetic, digital, or other means. Electronic data includes, but is not limited to, computer programs (whether private, commercial, or work-in-progress), programming notes or instructions, activity listings of electronic mail receipts and transmittals, output resulting from the use of any software program, including word processing files generated using programs such as Word or WordPerfect; spreadsheets and tables such as Excel or Lotus 123 worksheets; accounting application

data such as QuickBooks, Money, or Peachtree data; databases such as Access, Oracle, SQL Server data, or SAP; charts, graphs and outlines; electronic mail and other digital communications such as e-mail, voicemail and instant messaging; images and facsimile files; sound recordings such as .WAV and .MP3 files; video and animation such as AVI and .MOV files; contact and relationship management data such as Outlook and ACT; calendar and diary application data such as Outlook PST and blog entries; online access data such as Temporary Internet Files, History and Cookies; presentations such as PowerPoint and Corel Presentations; network access and server activity logs; project management application data; computer aided design/drawing files; backup and archival files such as VERITAS, Zip and .GHO; operating systems, source code of all types, peripheral drivers, PIF files, batch files, ASCII files, and any and all miscellaneous files and file fragments, regardless of the media on which they reside and regardless of whether said electronic data consists in an active file, deleted file or file fragment. Electronic data also includes any and all items stored on computer memories, hard disks, floppy disks, CD-ROMs, e-mail server stores such as Lotus Domino .NSF or Microsoft Exchange .EDB, removable media such as Zip disks, Jaz cartridges, Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, EPROM, PROM, RAM and ROM, on or in any other vehicle for digital data storage and transmittal. Furthermore, the term electronic data includes the file, folder tabs and containers and labels appended to, or associated with, any physical storage device associated with each original and copy.

g. "Electronic media" means any magnetic or other storage media device used to record electronic data. Electronic media devices include, but are not limited to, computer memories, hard disks, floppy disks, CD-ROM, removable media such as Bernoulli Boxes

and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, EPROM, PROM, RAM and ROM, or on or in any other vehicle for digital data storage and transmittal.

h. "Identical Copy" means:

i. A full and complete copy of the original Document that does not differ from the original paper Document because of highlights, comments, annotations, marks, transmission notations, underlining, marginalia, total pages, attachments, notes, markings or other alterations of any kind. Each such differing copy shall itself be considered an original paper Document and not an Identical Copy. For example, where there are two documents with identical content but one has highlighting and the other does not, in such a situation, the two documents shall not be considered identical.

ii. An electronic Document that is a copy of the original electronic Document including Metadata. Identical copies of the original electronic Document will generate the same MD5 Hash value. For example, an Identical Copy would include copies of the same Document saved on an individual custodian's local hard drive or an accessible network shared drive. An Identical Copy would not include copies of the same Document found in two individual custodians' produced Documents.

i. "Including" or "includes" means including, without limitation.

j. "Metadata" means: (i) information embedded in or associated with a native file that is not ordinarily viewable or printable from the application that generated, edited, or modified such native file which describes the characteristics, origins, usage and/or validity of the electronic file; and/or (ii) information generated automatically by the operation of a computer or other information technology system when a native file is

created, modified, transmitted, deleted or otherwise manipulated by a user of such system.

k. "Person" means any natural person or any business, legal, or governmental entity or association.

2. The following rules of construction apply to all discovery requests:

a. The terms "all" and "each" shall be construed as all and each;

b. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope;

c. The use of the singular form of any word includes the plural and vice versa; and

d. Requests that are stated in the present tense include the past tense and those in the past tense include the present tense.

### **INSTRUCTIONS**

1. Each Request refers to documents in the custody, control, and possession of GALBRAITH LABORATORIES, INC., ("GALBRAITH LABORATORIES, INC."), or known to GALBRAITH, as well as in the custody, control, and possession of or known to GALBRAITH'S counsel, representatives, agents, servants, investigators, contractors, and consultants, and unless otherwise privileged, their counsel, employees, representatives, agents, servants, investigators, contractors, and consultants.

2. If any document responsive to these requests is unavailable, because it was lost, altered, deleted, or destroyed by GALBRAITH or its agents, or for any other reason, GALBRAITH shall fully identify the document and also state:

- a. When and where it was lost, altered, deleted, or destroyed, or why it is otherwise unavailable;
- b. The name and address of each person who lost, altered, deleted, or destroyed it, or who otherwise caused it to be unavailable;
- c. The name and address of each person who directed, approved, or knew of its alteration, deletion, or destruction, and
- d. The name and address of each person who has knowledge of this document.

3. If you cannot produce a document that is responsive to these requests for any other reason, please respond to the extent possible, stating each reason why you cannot respond in full.

4. These requests shall be deemed to be continuing, to the full extent required or permitted under the Federal Rules of Civil Procedure, so as to require supplementary production when GALBRAITH or its agents obtain access, custody, possession, or control of any document not previously produced, which is responsive to any of these Requests.

5. Pursuant to FRCP 26(b)(5), any document falling within the scope of this Request that is withheld on the basis of a claim of privilege, work product, or any other ground is to be identified in writing and must include: a statement of the ground alleged for withholding such document; the Bates range of the document; its date; the identity of its author, recipients, and signatories; the type of document (e.g., letter); a summary of its contents; its present location; and, its custodian(s). Notwithstanding the assertion of an objection, any purportedly

privileged document containing non-privileged matter must be disclosed with the purportedly privileged portion redacted, with the redacted portion indicated on the document itself and listed on the privilege log to be provided pursuant to this paragraph.

6. Documents are to be produced in full and in their unexpurgated form. Redacted documents shall not constitute compliance with these Requests, unless such documents are properly redacted pursuant to a valid claim of privilege or work product as set forth in paragraph 5 above.

7. All documents produced in response to these Requests shall be organized and labeled either to correspond with the number of the specific request to which the documents are responsive or shall be produced in the order, format, and manner in which they are kept in the usual course of business.

8. Unless otherwise set forth, the relevant time-period for each Request is from the beginning of time to the present.

#### **DOCUMENTS TO BE PRODUCED**

1. Policies, procedures, rules and/or guidelines regarding Your document and record management, including the retention, storage and/or destruction of relevant (or potentially relevant) documents for such time that there exists a reasonable expectation of foreseeable litigation in connection with such documents.

2. Any and all contracts, communications, invoices, purchase orders, agreements, or other documents between You and Ethicon, Inc. related to the sale of mesh for use in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

3. Any and all documents which relate to, refer to, or embody patents and patent applications for any mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

4. Any and all documents related to, refer to, or embody licensing agreements and/or manufacturing agreements for any mesh sold by You to Ethicon, Inc.

5. Any and all documents related to, refer to, or embody company operating policies/procedures and/or protocols for any mesh sold by You to Ethicon, Inc. Inc. This request specifically includes documents containing information related to use of Your policies/procedures and/or protocols referencing International Organization for Standardization standards and/or guidelines, documents referencing quality control, biocompatibility, cytotoxicity, sterilization, winding, cleaning, knitting, batching, handling, storage and transportation of medical goods, cleaning, handling of materials used in mesh products sold to Ethicon, Inc., component scouring instructions, knitted fabric counts, thickness testing, ball burst testing, and elasticity testing.

6. Any and all documents related to, refer to, or embody regulatory rules and/or guidelines. This request specifically includes documents containing information related to your incorporation and utilization of U.S. Food and Drug rules, regulations or guidelines, including International Organization for Standardization (ISO) 10993, "Biological Evaluation of Medical Devices", guidance documents released by the FDA, Blue-Book Memorandum #G95-1, "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing", and standardization protocols/guidelines issued by the Organization for Economic Cooperation and Development (OECD), U.S. Pharmacopoeia (USP), and the ASTM

International (formerly known as the American Society for Testing and Materials) for any mesh sold by You to Ethicon, Inc. Inc.

7. Any and all documents relating, referring to or embodying communications between You or any agent or consultant of Yours, and the FDA or any other foreign or domestic governmental agency, regarding the manufacture of mesh sold by You to Ethicon, Inc., and any material or component manufactured by a third party. This request specifically includes documents relating to FDA Enforcement Inspection Reports (EIR) and all documents relating, referring to or embodying any warnings, objections or criticisms by the FDA and/or any foreign regulatory authority concerning the manufacture of any mesh sold by You to Ethicon, Inc., including audits, notices or inspections related thereto.

8. Any and all documents related to the creation or development of design specifications for the manufacture of mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any specifications for all materials manufactured by You and any material or component manufactured by a third party.

9. Any and all documents concerning any proposed or implemented changes to the design specifications for the manufacture of mesh sold or to be sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any proposed or implemented changes to the design specifications for all materials manufactured by You and any material or component manufactured by a third party.

10. Any and all documents related to the manufacturing specifications of mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

11. Any and all documents related to the manufacturing protocols for mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

12. All documents concerning the manufacturing process for any component, part, or material which was sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any manufacturing process for all materials manufactured by You and any material or component manufactured by a third party, including but not limited to:

- a. Structure and components;
- b. Spacing and size of the mesh's pores;
- c. Coating of the mesh;
- d. Heating of the mesh components or finished mesh
- e. Type of weave;
- f. Stiffness of mesh;
- g. Chemical, textile, and metallurgical components and composition;
- h. Packaging; and/or
- i. Sterilization

13. All documents concerning any proposed or implemented changes in the manufacturing process for the manufacture of the mesh sold by You to Ethicon, Inc. for

inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence, including, but not limited to:

- a. Structure and components;
- b. Spacing and size of the mesh's pores;
- c. Coating of the mesh;
- d. Heating of the mesh components or finished mesh
- e. Type of weave;
- f. Stiffness of mesh;
- g. Chemical, textile, and metallurgical components and composition;
- h. Packaging; and/or
- i. Sterilization

14. Any and all documents related to the testing, inspection, and/or analysis of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

15. Any and all documents related to the testing, inspection, and/or analysis of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence to determine whether it conformed to Ethicon, Inc.'s design and/or manufacturing specifications.

16. Any and all documents related to the inspection, analysis, and quality control of any component, part, or material used in the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence, including but not limited to:

- a. Vendor History Logs;

- b. Engineering change orders;
- c. Technical Report Advisory Sheets;
- d. Certificates of Conformance;
- e. Articles of First Inspection (AFI);
- f. Component Services Lab Test Request form;
- g. Component Services Lab Test Reports;
- h. Deviation Authorization Forms (DRs); and/or
- i. Material Reject Records (MRRs).
- j. Shop order transaction audit reports; and/or
- k. Testing.

17. Any and all documents related to any agreement by Ethicon, Inc. to accept mesh manufactured by You that deviated from Ethicon, Inc.'s design and/or manufacturing specifications.

18. Any and all documents relating to quality assurance and/or quality control protocols, procedures and/or analyses and/or changes to the manufacturing process of any component, part, or material used in mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any quality assurance and/or quality control protocols, procedures and/or analyses and/or changes to the manufacturing process for all materials manufactured by You and any material or component manufactured by a third party, including but not limited to quality control inspection reports, audits, compliance documents.

19. Any and all documents related to the Design Freeze, the Design and Development Plan, Design Input, and/or the Verification/Validation Test Plan prepared by Ethicon, Inc. for

mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

20. Any and all documents that relate to Ethicon, Inc.'s efforts to discuss, confirm, understand, or assess whether You manufactured mesh in accordance with its design and/or manufacturing specifications.

21. Any and all documents regarding the identity of any third parties or vendors which participated in the design or manufacture of any component, part, or material used in mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence. This request specifically includes documents containing information on any third party or vendor for all materials manufactured by You and any material or component manufactured by a third party, including but not limited to the North American Science Associates, Inc. (NAMSA).

22. Any and all documents pertaining to any third parties or vendors which participated in the design or manufacture of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence including, but not limited to design specifications, manufacturing specifications, protocols, quality assurance and/or quality control protocols, contracts, delivery and shipping schedules, testing, and pricing. This request includes, but is not limited to, documents that reference, contain, or relate to communications between You and any third parties or vendors which participated in the design or manufacture of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

23. Any and all standards utilized or relied upon by You or any third party or vendor in the design or manufacture of the mesh sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

24. Any and all documents related to inspection, evaluation and certification of Your quality management system by National Science Foundation (NSF) International Strategic Registrations.

25. Any and all documents that relate to inspections, audits, or evaluations of Your manufacturing facilities, equipment, processes, or procedures, by employees, agents, contractors, and/or representatives of Ethicon, Inc.

26. Any and all documents, minutes or notes of meetings relating to, or in any way pertaining to, the efficacy of mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

27. Any and all documents, minutes or notes of meetings relating to, or in any way pertaining to, risk or safety discussions, questions, or concerns associated with the mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

28. Any and all documents, minutes or notes of meetings relating to, or in any way pertaining to, adverse events associated with the mesh sold by You to Ethicon, Inc., for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

29. Any and all documents pertaining to confidentiality, non-compete, and/or non-disclosure agreements between You and Ethicon, Inc.

30. Any and all documents related to payments made by Ethicon, Inc. to You for the purchase of mesh and/or other material sold by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence

31. Documents sufficient to identify Your quarterly and yearly gross and net revenues from the sale of mesh and/or other material by You to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

32. Documents sufficient to identify what percentage of Your quarterly and yearly total sales were composed of sales made by You to Ethicon, Inc. for the years You sold mesh to Ethicon, Inc. for inclusion in products used in the treatment of pelvic organ prolapse and/or stress urinary incontinence.

33. Any and all documents evidencing any indemnification agreements between You and Ethicon, Inc.